

Study Protocol

Clinical Trial/Research Approval

NTUH-REC No.:202604050RINE

Date of approval:Jun 29, 2026

Title of protocol:Developing and Testing the efficacy of AI-Chatbot-Based Delivering Body-Mind-Spirit integrated with Mindfulness Compassion Therapy in improving holistic well-being and depression for Breast Cancer Survivors: A large-scale multi-sites study

Trial/Research Institution:National Taiwan University

Department/ Principal Investigator:School of Nursing/ProfessorHsiao Fei-Hsiu

The protocol has been approved by the 31st meeting of Research Ethics Committee E of the National Taiwan University Hospital on May 15, 2026. The committee is organized under, and operates in accordance with, the Good Clinical Practice guidelines and governmental laws and regulations.

The duration of this approval is 12 months (from Jun 29, 2026 to Jun 28, 2027). The investigator is required to report Serious Adverse Events and Unanticipated Problems in accordance with the governmental laws and regulations and NTUH requirements and apply for a continuing review not less than six weeks prior to the approval expiration date.

Daniel Fu-Chang Tsai, M.D. Ph.D.

Chairman

Research Ethics Committee E



Background

Breast cancer is the leading cancer in women and about 20 million women are newly diagnosed as breast cancer patients (World Health Organization, 2021). In Taiwan, breast cancer is continually to be the highest incidence of women cancer. The high severe levels of depression occurred in breast cancer patients who received cancer diagnosis within one year (Maass et al., 2015). The study also found 23% newly diagnosed breast cancer patients' depressive symptoms achieved clinical significance (Chang et al., 2019). The review and meta-analysis studies revealed that there were about 30-40% of breast cancer women with depressive symptoms after active cancer treatments (Pilevarzadeh et al., 2019). The review study found that although depression and anxiety rates were higher in cancer patients than the general population, there is a lack of high quality study on mental health intervention for cancer patients after active cancer treatments especially, for long-term survivors and younger cancer patients (Niedzwiedz et al., 2019).

Brown et al.'s review study (2021) examined the effects of psychosocial nursing interventions provided by specialist breast cancer nurses. The interventions mainly consisted of providing education on managing treatment side effects and developing healthy lifestyle, psychological supportive listening to their fear of cancer recurrence and emotional distress, and education on coping with body image such as changing clothes and bathing suits in public. The interventions are mainly provided through telephone follow ups. The findings showed the small improvements in depression reduction and optimal quality of life after intervention and 12 or 18 months follow ups. The limited effects on depression and anxiety reduction might suggest having more therapeutic-based and more accessible technology-based psychosocial nursing interventions. Nurses viewed AI technology positively into nursing care to reduce their workload (Rony et al., 2024).

AI-Chatbots could provide the interactive and adaptive features of AI virtual assistants. The qualitative review study (Senthilmahesh et al., 2024) found that artificial intelligence (AI) has been integrated into oncology care through virtual assistants/chatbots to enhance patient care and

support. AI-chatbot in oncology care could effectively improve patient care and healthcare system because AI-chatbot makes healthcare information more accessible, and 24-hourly supports patients, real-time information and response to patients and families' queries, and reduces the health professionals' caring burden.

For emotional support, AI-Chatbot uses a large language model (LLM) interacting with patients and their families and provides real-time and continuous information about disease, treatment, symptom managements which are related to their emotional burden (Senthilmahesh et al., 2024). Moreover, AI-Chatbot could provide 24 hours supportive emotional responses such as reassurance, empathetic responses and advice on coping strategies, relaxation techniques to reduce cancer patients' stress and emotional distress. AI-Chatbot could reduce cancer patients' anxiety and sense of isolation significantly.

The limitations and challenges for future study of AI-Chatbot oncology care include information accuracy, enhancing the ability of emotional intelligence and the need for combining human intervention in particularly complex cases. AI-chatbot could not replace human professional care, therefore, human-in-loop escalation is suggested for managing the complex and high-risk cases. The future studies need to address these challenges to develop human-center care using complementary tools of AI chatbot technology in oncology nursing care.

The recent review (Mitsea et al., 2023) found that AI-Chatbots acts as a mindfulness coach, delivering personalized mindfulness and self-compassion training for emotional regulation skills. Notably, in this review, only two studies are based on cancer patients. Therefore, more AI-Chatbots mindfulness-based and compassion-based programs need to be developed for cancer patients.

For twenty-years, our team has developed and examined the effects of body-mind-spirit therapy integrated mindfulness and compassion-based therapy (BMS-MC) for breast cancer survivors, lung cancer survivors and their family caregivers. Although we found the positive effects of BMS-MC in reducing depression, and improving holistic well-being, our person-to-person group therapy design could not be accessible to more cancer survivors. AI-Chatbot, a technology-enabled solution, can be a good chance to scale intervention and offer self-arrangement and practice into daily life. Therefore, in this study, we intend to conduct a large-scale study: develop and test AI-Chatbot-based BMS-MC for breast cancer survivors through Taiwan's breast cancer organizations. In Taiwan, Line platform is commonly used in people's daily life, therefore, our BMS-MC AI-Chatbot will be provided in Line platform.

This study will address the limitations of the previous studies on AI-Chatbot oncology care including lack of emotional regulation program, and combining human-in-loop escalation for complex cases, and using EEG feedback in AI-Chatbot to enhance their motivation and measure brain status. This study addresses these challenges to develop human-center care using AI chatbot technology in oncology nursing care.

Mindfulness and empowerment-based psychotherapy have been provided via AI-chatbot for breast cancer survivors. Nevertheless, the psychotherapy using holistic well-being approach has not been well-developed and provided via AI-Chatbot. Our team has developed a holistic nursing care program using holistic body-mind-spirit integrated psychotherapy integrated with mindfulness compassion therapy (BMS-MC) for breast cancer and lung cancer survivors, and their family caregivers (Hsiao et al., 2012; Hsiao et al., 2016; Hsiao et al., 2022; Hsiao et al., 2025a; Hsiao et al., 2025b). Our long-term follow ups found that our BMS-MC consistently demonstrates to produce the positive long-term effects on psychological well-being (QOL functions and symptom distress, actively searching for meaning in life, secure attachment styles in close relationships) and

maintaining stable physical stress responses to everyday life stress (steeper diurnal cortisol patterns). The main findings from our previous studies are summarized below:

Delivering BMC-MC via AI-Chatbot and developing feedback system based on our BMS-CM group therapy experiences and update literature of positive psychology, mindfulness and self-compassion

Based on our previous findings, we have developed the effective BMS-MC group therapy for breast cancer survivors. Nevertheless, the person-to-person group design could not be accessible to more cancer survivors. Therefore, for this research proposal, we intend to overcome this limitation and develop and examine its effects and feasibility on BMS-MC via the prompt-guided LLMs AI-Chatbot program for a large-scale service for breast cancer survivors. Our BMS-MC AI-Chatbot using an retrieval-augmented generation (RAG) will be provided in the Line platform to step by step guide breast cancer survivors to practice BMS empowerment, mindfulness and compassion skills in their daily life. Their practices will also provide the feedback based on our feedback to survivors in group therapy experiences and literature of positive psychology, mindfulness and self-compassion. Their emotions will be supported by AI-Chatbot with human-loop escalation to ensure their severe emotions will be intervened directly by the PI or transferred to mental health services.

The Purposes of the 3-year proposal:

1. Developing the customized the prompt-guided LLMs AI-Chatbot (CalmMindRecoveryJourney)” using an retrieval-augmented generation (RAG) to deliver BMS-MC therapy for breast cancer survivors.
2. Adopting a mixed-methods design to evaluate the feasibility, acceptability, safety, and preliminary efficacy of the AI-Chatbot
3. A randomized waitlist controlled trial (RCT) to compare the effects of AI-Chatbot in the outcomes of holistic well-being, severity of insomnia, and depressive levels, mindfulness status, self-compassion, emotional regulations, meaning in life, and breast cancer-specific QOL, and their active or calm brain status indicated by EEG frontal lobe presentation between the experimental and waiting list control group in the 6th week AI-Chatbot guided BMS-MC and the effects will be maintained in the 12th (experimental) and 18th (control) week follow-up time.
4. Qualitative explorations of the experiences of participants’ using AI-Chatbot

Method

Developing and evaluation of the feasibility, acceptability, safety, and preliminary efficacy of customized AI-Chatbot

The study consists of two phases: Phase I Develop a the prompt-guided LLMs AI-Chatbot using retrieval-augmented generation (RAG) to deliver BMS-MC, feedback system, 24-hour emotional support with human-loop escalation and Phase II Pilot evaluation using a mixed-methods design of feasibility and preliminary efficacy of Chatbot BMS-MC intervention.

Phase I : Developing CalmMindRecoveryJourney AI-Chatbot-based intervention delivering BMS-MC

Modules and each session contents of BMS-MC intervention

CalmMindRecoveryJourney is a the prompt-guided LLMs AI-Chatbot implemented through Line platform which guides survivors step by step complete 6-week Modules: BMS empowerment strategies, Structured Mindfulness skills and Compassion-based skills. The modules for each session contents will be developed based on our previous intervention studies on BMS-MC for breast cancer survivors, lung cancer survivors and their caregivers (Hsiao et al., 2012; Hsiao et al.,

2016; Hsiao et al., 2022; Hsiao et al., 2025a; Hsiao et al., 2025b), and update literature review. BMS-MC consists of BMS empowerment strategies and mindfulness/compassion to enhance breast cancer survivors' holistic well-being and emotional regulation skills (mindfulness, self-compassion) (table 1).

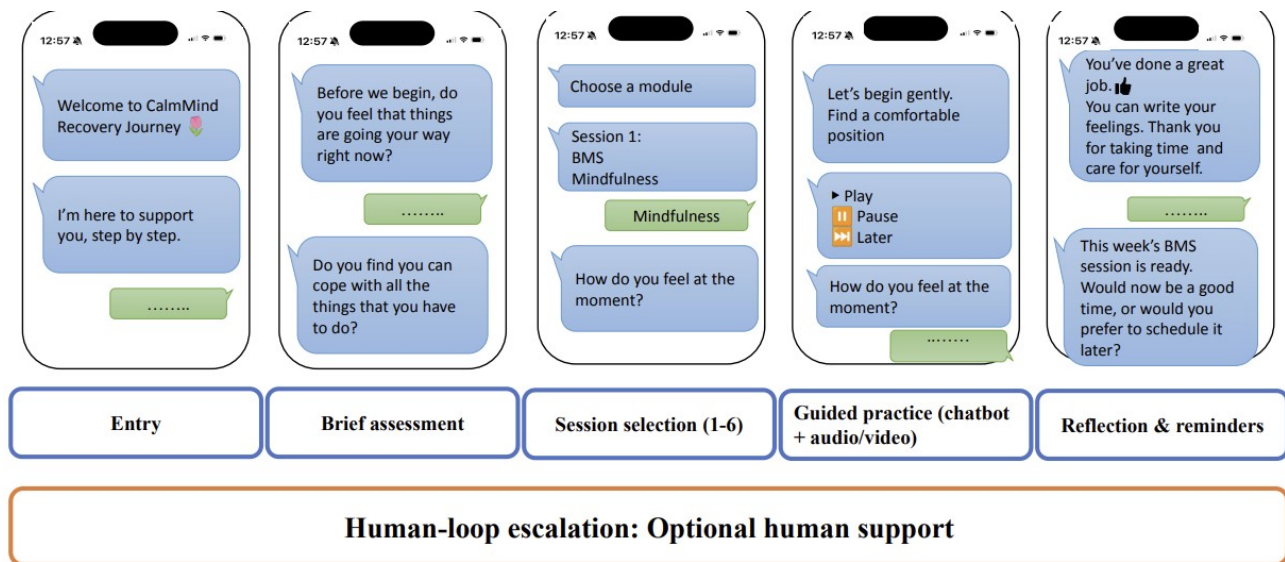
Table 1. The content outline for 6-week BMS-MC

Weekly module	Themes	Objectives & Activities
1~2	On a journey of recovery BMS: Toward holistic health	Psychoeducation about BMS: Introduction of the integrative holistic health concept and holistic empowerment strategies Practicing physical strength: Qigong, Planning healthy lifestyle (exercise, diet, and sleep hygiene)
	Mindfulness: Awareness, Attention regulation	Lecturing to understand mindfulness and self-compassion: Introduction of the objectives and contents of this program, group members, What are mindfulness and self-compassion: The crazy brain and emotional regulation through empowering the soothing system by mindfulness and compassion skills Practicing Mindfulness skills: mindfulness breathing, body scan with nature meditation, attention trainings: attention to different visual fields, savoring
3~4	BMS: Transformation from suffering to growth experiences	Understand the nature of loss and gain in the life :The loss and gain in the road of life, personal and family growth Learn about mind strength: painting a picture of “my breast”, and my inner strength
	Self-compassion love-kindness	Lecturing to understand self-compassion: Being self-compassion is not a weak person, different from self-pity, The impact of self-compassion on emotional regulation, The steps toward self-compassion Practicing Self-compassion skills for self-acceptance Affectionate soothing breathing, mindful compassion awareness, Self-compassionate imagery via creating a safe place, compassionate colors: love-kindness meditation, compassion voice and toughing
5~6	BMS: Reconstructing the meaning of life and restructure life priority My growth and strength	Understand forgiveness as the wise choice of free self from suffering A letter to the significant other; four saying to the person I love: “I’m Sorry, Please Forgive Me, Thank You, I Love You” Learn about death as a mentor teaching life cannot wait , sharing the story about die in peace Learn about letting go of attachments and desires let go and new life planning/my dream and painting a gift for “my breast”
	Self-compassion Meet the difficult emotions and through self-compassion practice	Lecturing to understand the nature and causes of suffering and the role of self-compassion in self-healing: The first arrow: the stress events The second arrow, cause of suffering: harmful responses to the stress events (self-criticism, guilt, anger) The self-compassion replacing the harmful responses Practicing the identification of first and second arrows and self-compassion skills for self-kindness: love-kindness meditation with touching, Compassionate imagery (from self-compassion to receiving

		compassion from others) Practicing appreciation: Gratitude for everyday life
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Chatbot-mediated conversational structure

Figure (below) is our proposed conversational flow structure that will be developed based on our papers, our group therapy experiences and update papers related to mindfulness, compassion and positive psychology.



- **Assessment:** (1) Before entering the module, participants will be assessed for momentary perceived stress and emotion ratings. Two items of Perceived stress scale (Cohen et al., 1983) will be used to measure: “Do you feel that things are going your way?” and “Do you find you can cope with all the things that you have to do?” The scales are visual analog scales ranging from 0=“not at all” to 100=“very much.”
- **Session selection:** Guiding survivors to enter each module and practice lessons: AI-Chatbot providing the step by step instruction to complete each module but remaining flexible, participants can also have their own preference to enter the module. *They will also be reminded that a human-coach (by the principal investigator) is also available* when virtual assistance cannot help them.
- **Guided practice:** Before entering a mindfulness session, “How present do you feel at the moment?” and “How aware are you of your own body at the moment?”. They will be guided to use video files to learn concepts and use audio files to practice.
- **Reflection and Reminders:** For Mindfulness and compassion Sessions, AI-Chatbot will notify participants once a day (flexible timing) for practice with approximately 10-20 minutes for five days in a week, and for BMS module, AI-Chatbot will notify participants for practice once a week for approximately 30-40 minutes. Participants can choose to postpone practice after receiving text message reminders. Participants are also reminded they are welcome to practice more frequently via audio files on Line platform.

Establishing AI-Chatbot feedback system and analytic system

Feedback systems consist of feedback to their practices of BMS-MC and provide emotional support. The system will be built up based on our group therapy experiences and literature of BMS, positive psychology, mindfulness and self-compassion.

Developing human-in-the-loop escalation system for complex or high-risk cases

The human-in-the-loop escalation system will identify complex or high-risk cases to ensure AI-

Chatbot will notify PI about participants' condition and PI will directly contact these cases within 24-hour to further assess, support or transfer to face-to-face human mental health professionals.

Phase II Evaluation of feasibility and preliminary efficacy of AI-Chatbot BMS-MC intervention

Design: This study will adopt a mixed-methods design to evaluate the feasibility, acceptability, safety, and preliminary efficacy of the intervention. The 12-week AI-Chatbot intervention includes 6-week AI-Chatbot guided BMS-MC and continues with self-practices for the other 6 weeks. The mixed-methods design includes the quantitative (a randomized waitlist-controlled trial, RCT) and qualitative methods (individual in-depth interview).

A randomized waitlist-controlled trial (RCT) with repeated measures will be conducted to quantitatively evaluate the efficacy of the 6-week AI-Chatbot guiding BMS-MC program and the other 6-week self-practices in improving breast cancer survivors' holistic well-being and coping skills, and their active or calm brain status indicated by frontal lobe presentation. The 80 breast cancer survivors who completed active cancer treatments will be randomly assigned into two groups: the experimental group (安心復原旅程 AI-Chatbot), and the waitlist control group (no intervention while waiting).

The qualitative data will be collected by using individual in-depth interviews after completing the follow up period at the 12th-week. The qualitative data will offer the participants' experiences of how AI-Chatbot provides support and helps them to improve well-being, and feedback of the AI-Chatbot such as responses to their query and support for their emotions.

Participants:

Inclusion criteria of the survivors: diagnosed as breast cancer; completing the active cancer treatments (surgery, chemotherapy, radiotherapy), aged at least 20, owned a smartphone (Android or iOS) with Line access, Ability to communicate with the AI chatbot, Willingness to participate in the research and interact with the AI-chatbot during the intervention.

Exclusion criteria: diagnosis of another type of cancer, current receipt of psychotherapy, and another online psychosocial or mental health intervention, and the presence of cognitive impairment or severe mental health conditions that could limit the ability to understand or engage in the intervention.

Participants will be recruited from breast cancer patient no-profit organizations, social media platforms such as Facebook and Instagram.

Sample sizes: Sample size was estimated using G*Power for a two-arm randomized controlled trial with two measurement occasions (baseline and post-intervention), focusing on the group-by-time interaction. Assuming a medium effect size (Cohen's $f = 0.25$), a two-sided significance level of 0.05, power of 0.95, and a correlation of 0.50 between repeated measures, the required sample size was 64 participants with complete data (32 per group). Allowing for an anticipated attrition rate of approximately 20%, we will recruit a total of 80 participants (40 per group). This sample size is sufficient to evaluate feasibility outcomes and to estimate the magnitude of preliminary intervention effects to inform the design of a subsequent trial.

Randomization and Blinding

After all participants complete the baseline measurement, simple random assignment will be used to randomly assign them to the experimental or waitlist control group in a 1:1 ratio by the independent researcher. About allocation concealment, this independent researcher will keep the outcome of allocation in the word document with password to protect the randomization process. Single blinding will be adopted to avoid subjects from knowing which group they are in the experimental

or waiting-list control group. The research assistant who entered and checked the outcome data is blinded to the randomization process.

Study procedure:

Recruitment: This study inviting information will be sent to breast cancer organizations.

Baseline assessment: The participants who meet the inclusion criteria and show interest in understanding this project, will be contacted about the detailed information about this study by the research assistant via phone, Line, or in person. After signing the consent form, they will be invited to complete the baseline measures through Google Forms or mailing.

Intervention stage: They will be invited to participate in the online meeting to instruct about how to use and interact with our AI-Chatbot and wearable EEG when practicing mindfulness and self-compassion breathing and meditation at home. We will explain during the first 6-week, how the AI-Chatbot system virtual assistance will guide them to step-step complete the BMS and mindfulness, and self-compassion. They will be reminded to wear the portable EEG while they practice breathing and mediation at home. *They will also be reminded that a human-coach (by the principal investigator) is also available* when virtual assistance cannot help them. They can give their subjective feedback on the AI-Chatbot system at any time.

End of BMS-MC assessment: After six weeks, they will be invited to complete a postintervention assessment and provide their subjective feedback on the AI-Chatbot system. They will be asked to complete the post-intervention assessments.

The follow up period (self-practice): After completing the postintervention assessment, they will be invited to continue with BMS-MC practices at home for 6 weeks.

Follow up assessment: After 6-week self-practice, they will be invited again to complete the follow up assessments and will also be invited to participate in the individual online or person to person interview to understand their learning and using AI-Chatbot experiences.

Outcome measures: The outcomes include self-report questionnaires, wearable EEG online data and survivors' learning process data from the AI-Chabot system including adherence and engagement with AI-Chatbot.

Self-report questionnaires

The outcome measures include primary outcome (WHO Well-Being Index and Patient Health Questionnaire-9, PHQ-9), secondary outcomes (Severity of insomnia questionnaire, Emotion Regulation Questionnaire, Five Facet Mindfulness Questionnaire, self-compassion scale, meaning in life, EORTC QLQ-BR45 breast cancer specific complementary measure, and Feasibility-related program engagement and adherence.

- Subjective Well-Being The 5-item WHO Well-Being Index was used to assess subjective well-being. Participants responded on a 5-point Likert scale ranging from 5="all of the time" to 0="at no time." A total sum score (range 0-100, with 100 indicating the best well-being) was calculated from raw scores (range 0-25) and multiplied by4.
- The Insomnia Severity Index (ISI) is a commonly used 7-item questionnaire that measures the severity of insomnia symptoms and their impact on daily functioning. Each item is rated 0-4, giving a total score from 0-28. The scores ≥ 15 are indicated as the threshold for clinically significant insomnia.
- The Patient Health Questionnaire-9 (PHQ-9) measures depressive symptoms (Spitzer et al. 1999). The PHQ-9 is responded on the scale of "0" (not at all) to "3" (nearly every day). The levels of depression are classified into not unlikely (1-4), mild (5-9), moderate (10-14), moderate to severe (15-19) and very severe (20-27). The score of 10 is used as a cut-point for clinical depression. This scale is reliable and valid. Cronbach's α above 0.9.

- Emotion Regulation Questionnaire was used to assess emotion regulation. The 10-item questionnaire included 6 items representing emotion regulation strategy reappraisal and 4 items assessing emotion regulation strategy suppression, rated on a 7-point Likert scale ranging from 1=“strongly disagree” to 7=“strongly agree.” Accordingly, the mean scores reflect the use of and preferences for various emotion regulation strategies.
- The 15-Taiwanese Five Facet Mindfulness Questionnaire (T-FFMQ) developed by Baer et al. (2006) and translated by Huang et al. (2015) consists of five dimensions of mindfulness status (1) observing: noticing or attending to internal and external experiences; (2) describing: labelling internal experiences with words; (3) acting with awareness: attending to one's activities of the moment (opposite of acting on automatic pilot); (4) nonjudging of inner experience: taking a nonevaluative stance toward thoughts and feelings; and (5) nonreactivity to inner experience: allowing thoughts and feelings to come and go, without getting caught up in or carried away by them. This scale is responded to on the scale ranging from 1 “disagree strongly” to 5 “agree strongly.” The higher scores indicate higher mindfulness levels. T-FFMQ has been tested in Taiwan with good reliability and validity.
- The 13-item Self-Compassion Scale Short Form (SCS-SF) (Raes et al., 2011). The SCS-SF has two subscales: Self-disparagement and Self-care. This scale is developed to measure people’s capacity for self-compassion – the ability to hold one’s feelings of suffering with a sense of warmth, connection and concern. This scale is responded to on the scale ranging from 1 “almost never” to 5 “almost always.” The higher scores indicate higher mindfulness levels.
- Meaning in Life The Meaning in Life Questionnaire (MLQ; Steger et al., 2006) is a 10-item questionnaire to measure the presence of meaning and the searching for meaning in life. Presence items examine how much participants feel their lives have meaning. Search items are concerned how much participant strive to find meaning and understanding in their lives. Participants rate each item from 1 (absolutely untrue) to 7(absolutely true). Higher scores indicate higher levels of presence of meaning or search for meaning.
- The QLQ-BR45 assess body image, sexual functioning, breast satisfaction, systemic therapy side effects, arm and breast symptoms, endocrine therapy symptoms, skin mycosis symptoms, endocrine sexual symptoms, and three single-item to assess sexual enjoyment, future perspective and being upset by hair loss. The range in score from 0 to 100. Higher scores indicate higher levels of functioning and symptom distress.
- Survivors Information Questionnaire: This questionnaire will be developed by researchers including gender, age, level of education, religion, family history of cancer, time of diagnosis and completing treatments.

Survivors’ learning process data from the AI-Chabot system including adherence and engagement with AI-Chatbot

- Feasibility-related Program engagement and adherence: The total number of sessions will be calculated as the count of all sessions for an individual user, and the total interaction time with the chatbot from the start to the end of a session summed across all sessions. AI-Chatbot Feedback users will be asked to rate how helpful they find the lesson of the day on a scale from 0 (“not really”) to 10 (“yes, very much”). Participants will be invited to provide open-ended feedback about the chatbot program such as how much they enjoy the chatbot and what they find particularly valuable or not valuable, about their opinions of the strengths and weaknesses, and suggestions for improving this intervention. Safety: adverse events reported by the participants in association with Chatbot or other participation processes. Participants are encouraged to report any problem with using Chatbot.
- Examining survivors’ learning process from AI-Chatbots system generating records what information was extracted by participants, their home works and also summaries of

interactions with AI-Chatbots.

Wearable EEG online data

- The headband portable wearable EEG device: this is used to monitor the participants' brain state by measuring EEG signals at frontal and temporal locations, when they practice mindfulness and self-compassion breathing and meditation. These signals use algorithms to define between active and calm states. The participants' data are collected directly by the device. The data will be uploaded to a secure cloud server.

The qualitative assessment of the feasibility, usability, and acceptability)

The qualitative data will be collected by using individual in-depth interviews after completing the study. The qualitative data will offer the participants' experiences of how AI-Chatbot provides support and helps them to improve well-being, and feedback of the AI-Chatbot such as responses to their query and support for their emotions. The interviews will be provided by research assistants with the training by the principal investigator (Professor Hsiao) who has been trained in the qualitative methodology. Questions are formulated to cover the feasibility, usability, and acceptability of the supportive program. The questions interviewing guide may be used to be further exploring users' experiences in Table 1. The interview will be audio taped and will be then transcribed and analyzed for emerging themes using thematic analysis (Braun & Clarke, 2006). In addition to Co-PIs, an independent reviewer will also be invited to verify the validity and reliability of analysis.

Table 1. The interview guides

• What were your expectations regarding the AI-Chatbot? • How would you describe the AI-Chatbot? • How did you experience the AI-Chatbot? What did you experience positively/negatively? • What are particular (dis-) advantages of the AI-Chatbot? • How would you describe the AI-Chatbot in terms of structure and flexibility? • Was there anything particularly difficult to motivate yourself for? • Was there anything particularly difficult to engage in daily practice (mindfulness/compassionate exercise)? • Was there anything particularly helpful to engage in daily practice (mindfulness/compassionate exercise)? • What impact did the intervention have on your thoughts, feelings, plans, and behaviors? • Which component of the intervention do you think is the most important/ useful? • Is there anything (important) you would like to add to that you think I should have addressed?

Tentative timetable: Table 3 shows how this research project will be completed in three years.

Task	AI-Chatbot program											
	2026					2027						
	8	9	10	11	12	1	2	3	4	5	6	7
Phase I: Developing AI-Chatbots												
Phase II: Recruiting subjects & collecting data, clinical trial begin with testing effects of the programs for experimental and waitlist control groups	•	•	•	•	•	•	•	•	•	•	•	•
Monitoring the group process and performing follow-up evaluations												
Analyzing data and writing report for RCT												

results													
	2027							2028					
Recruiting subjects &collecting data, clinical trial begins with testing effects of the programs for experimental and control groups	•	•	•	•	•	•	•	•	•	•	•	•	•
Monitoring the group process and performing follow-up evaluations			•	•	•	•	•	•	•	•	•	•	•
The third year:Recruiting subjects &collecting data, testing effects in a large sample									•	•	•	•	
	2028							2029					
The third year:Recruiting subjects &collecting data, testing effects in a large sample	•	•	•	•	•	•	•	•	•	•	•	•	
Monitoring the process and performing follow-up evaluations	•	•	•	•	•	•	•	•	•	•	•	•	
Data analysis and writing up for the report										•	•	•	
Compile a AI-Chatbot manual for clinical professionals and breast cancer survivors											•	•	

Data analysis

All analyses will be conducted using SPSS Statistics version 21. Descriptive and univariate analyses will be performed to compare baseline characteristics and outcome variables between the intervention and waitlist control groups. An intention-to-treat principle will be applied, with missing data handled using available observed data without ad hoc imputation. Changes in outcome variables over time between the intervention and waitlist control groups will be examined using generalized estimating equation models, with repeated measurements specified for each follow-up assessment. These models account for within-subject correlations across time and allow inclusion of participants with incomplete follow-up data. Moderation analyses will be conducted using the PROCESS macro (Model 1; Hayes, 2018) to examine whether intervention effects vary according to participant demographic characteristics, disease-related variables, baseline psychological conditions, and intervention adherence and engagement. For statistically significant moderators, simple slope analyses will be performed to explore intervention effects at different levels of the moderator, defined as one standard deviation above and below the mean. Prespecified mediation analyses will be conducted using the PROCESS macro (Model 4; Hayes, 2018) to examine potential mediators of intervention effects. Because mediators and outcomes were assessed at the same measurement time points, mediation analyses will be based on change scores across the intervention period rather than assuming temporal precedence. The mediation model will specify intervention conditions as the independent variable, changes in mindfulness, self-compassion, emotional regulation, breast cancer-specific QOL, and EEG calmness as mediators, and changes in holistic well-being and depressive symptoms as outcomes, consistent with the intervention's theoretical framework. Indirect effects will be estimated using 5,000 bias-corrected bootstrap resamples, with statistical significance determined by 95% confidence intervals that do not include zero.

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